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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
FORD, JOHN M

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/986725	Applicant(s) Jensen et al
	Examiner T. M. Ford	Group Art Unit 1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on July 21, 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 4, 6, 8, 10, 12, 14, 16, 18, 20, 21, 26, 28-32 and 34 is/are pending in the application.

Of the above claim(s) 20, 21 and 28--32 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 4, 6, 8, 10, 12, 14, 16, 18, 26 and 34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing R view, PTO-948

☐ Other _____

Office Acti n Summary

Applicant's response of July 21, 2003, is noted.

The claims in application are claims 1, 4, 6, 8, 10, 12, 14, 16, 18, 20, 21, 26, 28—32 and 34.

Claim 1 cannot be allowed as it recites too many uses. It is not believable, on its face, that any one compound could have all of those uses. Many of the uses cited have no established regimen of treatment.

Claim 1 is, therefore, rejected under 35 U.S.C. 112, 1st paragraph. It would require undue experimentation on the part of the reader to determine what host-dosage relationship would be necessary to accomplish each treatment, individually.

Claim 1 recites a method comprising administering a therapeutically effective amount of a chemical compound having selective Ikca modulatory activity to said mammal. (Said mammal has no antecedent basis).

This utility statement is not acceptable, as it does not relate to the real World of Commerce. That appears to be a Laboratory test.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner vs Manson, in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practic employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility".

The utility statement "selective Ikca –activity", above noted, does not qualify as bringing into existence a practical "real world" utility.

SYNOPSIS OF APPLICATION OF THE REVISED INTERIM UTILITY GUIDELINES

It is assumed at the is point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that some "utility" is disclosed in the specification or is recognized to be well established in the art. The examiner should determine whether any asserted utility is specific and substantial, and if so, determine should consider whether or not there utility is credible and no rejection under 35 U.S.C. 101 should be made.

Guidance for Various Examination Situations

I) a) For method claims that recite more than one utility, if at least one Utility is credible, specific, and substantial, a rejection under 35 U.S.C. 101 should not be made. If any utility in such a claim not a specific and substantial credible utility, i.e., the claim encompasses at least one utility that does not meet the requirements of 35 U.S.C. 101, the rejection of the claim should be addressed under 35 U.S.C. 112, first paragraph, scope of enablement.

b) For product clams that do not recite any utilities, disclosure or

assertion of one specific, substantial and credible utility meets the criteria of 35 U.S.C. 101.

II) if no credible, specific, and substantial utility is asserted in the Specification and none is well established, a rejection under 35 U.S.C. 101. would be proper.

III) Cure or prevention – Utilities that constitute curing or preventing a condition are sometimes not credible to one of skill in the art and thus may raise a question under 35 U.S.C. 101. However, any rejection based on lack of credible utility must be supported by documentary evidence or sound technical reasoning.

IV) Treatment – Since most diseases or conditions can be treated., rejections Under 35 U.S.C. 101 for treatment claims should rarely be made.

V) Vaccines – Since vaccines are regularly prepared to combat various Viruses and organisms, vaccines would have a credible utility to one of skill In the art. Thus, vaccines, including those for small pox, should not raise a Question under 35 U.S.C. 101.

VI) Materials to be used for research, or methods of using those materials For research, raise issues of whether the utilities require or constitute carrying out further research. Raise issues of whether the utilities require or context of use. See., e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility."

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. Vs. Manson, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing , reasoning the patent system is related to the World of Commerce, rather than the realm philosophy, ibid, 148 USPQ at 696.

See the previous Office Action, applicants need to limit claim 1 to one reasonable believable utility, considered with 37 CFR 1.475 and PCT Rule 13.2.

Claims 4, 6, 8, 10, 12, 14, 16, 18, 26 merely recite compounds these claims are dependent on a rejected method claim, and, therefore, cannot be allowed. More importantly these claims recite no method language, other than preamble. These claims are completely limited to compound recitations. These claims are minimally defensive publications of compounds. These claims that recite only compound search through a method claim so broad and vague as to have no meaning. The prior art, therefore, can be said to meet the undescribed utility of the compounds. The claims are in fact a back door attempt to claim compounds, or minimally block others from obtaining these, by publishing them here.

Therefore, claims 4, 6, 8, 10, 12, 14, 16, 18 and 26 are rejected under 35 U.S.C. 103 as being unpatentable over prior art such as Brugnara 103.

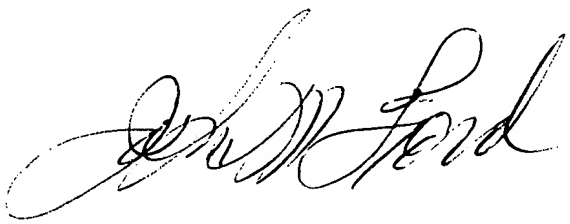
The compound of claim 34 is found in o.. 21 of U.S. Patent 6,028,103. Therefore, claim 34 and claim 1 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Patent 6,028,103. See col. 3, lines 15—20 and col. 8, lines 55—60, of the Patent. Since, such broad ranges of uses are alleged for claim 1 it becomes meaningless; method is obvious from the prior art.

Claims 28—32 stand withdrawn as they are directed to further additional active ingredients that would not be searched in the same place as claim 1 as it is not of the same scope. Further, these claims are dependent on cancelled claim 19.

Claims 20 and 21 stand withdrawn as they are not of the same scope as the claim from which they depend as they recite additional active ingredients. Claims 20 and 21 would require that the names for the immure-suppressing agent recited be converted to chemical structure and then classified on the basis of that agent: multiple different from claim 1, therefore, extremely burdensome as they are not of the same scope as claim 1, and control classification in different multiple areas dependent on the structure of the immune suppressing agent.

John M. Ford: jmr

September 8, 2003



JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624